BARRIER EFFECT EFFICACY TESTING FOR SKIN PROTECTION

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Skin is the largest organ of the human body. It is our first line of defense against external dirt, infections and other irritants that could potentially affect our health. Barrier protective products have been developed for skin protection that can ward off external harmful elements, which can penetrate the epidermis and cause untold damage to the skin. While skin barrier creams are not as popular as sunblock, anti-wrinkle and moisturising lotions, they still play an important role in protecting the skin from substances, such as corrosive and toxic liquids or chemicals. Skin barrier creams are also used as general hypoallergenic protection from skin allergies for people with sensitive skin, for example from diaper rash and bed sores. Repeated exposure of the skin to irritants and low temperatures or friction may lead to a gradual lowering of threshold for the disruption of the skin barrier and consequently to irritant-contact dermatitis (Korstanje, 2001).

Figure 1 shows an example of chafed skin while *Figure 2* illustrates the application of nappy rash cream. Barrier preparation products can be in the form of cream, ointment or aerosol spray and often contain substances such as silicone, zinc oxide or dimethicone which repel water. The lipid content and its moisturising components in the cream may influence skin barrier recovery (Buraczewska *et al.*, 2007).

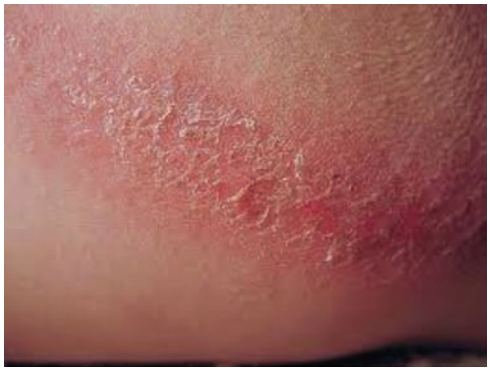

Figure 1. Chafed skin.

Figure 2. Application of nappy rash cream.

OBJECTIVES

In vivo barrier effect test service is set up to support the niche market of barrier-protective related products. Data on the effectiveness on the optimal protective effect is vital to support marketing claims that are in line with the Control of Drugs and Cosmetics Regulations 1984 as stipulated by the National Pharmaceutical Control Bureau.

METHODOLOGY

In vitro tests for assessing the protective ability of topical products generally have poor predictive value for the *in vivo* situation (Gehring *et al.*, 1994). Therefore, the best of human percutaneous absorption is determined by *in vivo* studies in humans (Zhai and Maibach, 2001).

An efficacy study on 20 human volunteers was carried out in MPOB. The initial basal reading was recorded after the volunteers were acclimatised under standard temperature and humidity. The skin areas on the volar forearm were marked and treated with barrier cream samples. Another two areas of the forearm marked as untreated and control respectively were left undisturbed. The test was based on an open patch test using small discs impregnated with 1% sodium lauryl sulphate (SLS) solution for 24 hr, which would induce skin barrier damage and the removal of skin lipids. These SLS impregnated discs were placed on 'treated' and 'untreated' areas, except the 'control'. Subsequently, the skin barrier repair was assessed after one week of application by monitoring the

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transepidermal water loss (TEWL), skin hydration and skin redness. Measurements were carried out on both treated and untreated areas at different time intervals at 5, 30 and 60 min after the discs were removed from the test areas.

Statistical analyses were done using Analysis of Variance (ANOVA), paired t-test and Tukey. A nine-day study is sufficient to determine the product efficacy and the relevant information is shown in *Table 1*.

An example of a barrier effect test of a product was carried out using a diaper cream containing zinc glycerolate and formulated by MPOB. All samples were initially recorded for moisture loss through high TEWL values when the skin barrier layer was disrupted by SLS (*Figure 3*). The product used was able to reduce TEWL after 30 and 60 min of application. ANONA indicated significance at 95% confidence level.

Table 2 shows the result of Tukey test on TEWL, which compares the skin areas treated with the samples (MPOB product) against the untreated areas. It is concluded that there are significant differences between untreated and treated areas at 60 min after SLS removal.

Treatment of normal skin for a week with the diaper cream containing zinc glycerolate and placebo cream slightly increased the skin hydration, in comparison with the areas treated with commercial diaper cream, including untreated and control skin areas as shown in *Figure 4*. However, there was no significant difference of the chromametric effect (*Figure 5*).

CONCLUSION

Short-term applications of MPOB diaper cream formulation have increased skin hydration properties and significantly prevented TEWL. The MPOB nappy rash cream performs equally well compared with that of the commercial cream. A histological assessment could better define the extent of skin damaged by SLS treatment and provide the mechanisms of protection of test creams.

TABLE 1. *In vivo* BARRIER EFFECT TEST, PROCEDURES, DURATION AND COST

Sample	Parameters	Duration	Cost
Twice daily application for nine days of 20 participants.	Transepidermal water loss (TEWL), skin hydration and skin redness are monitored throughout the study.	Nine days	RM 5900 in 2013

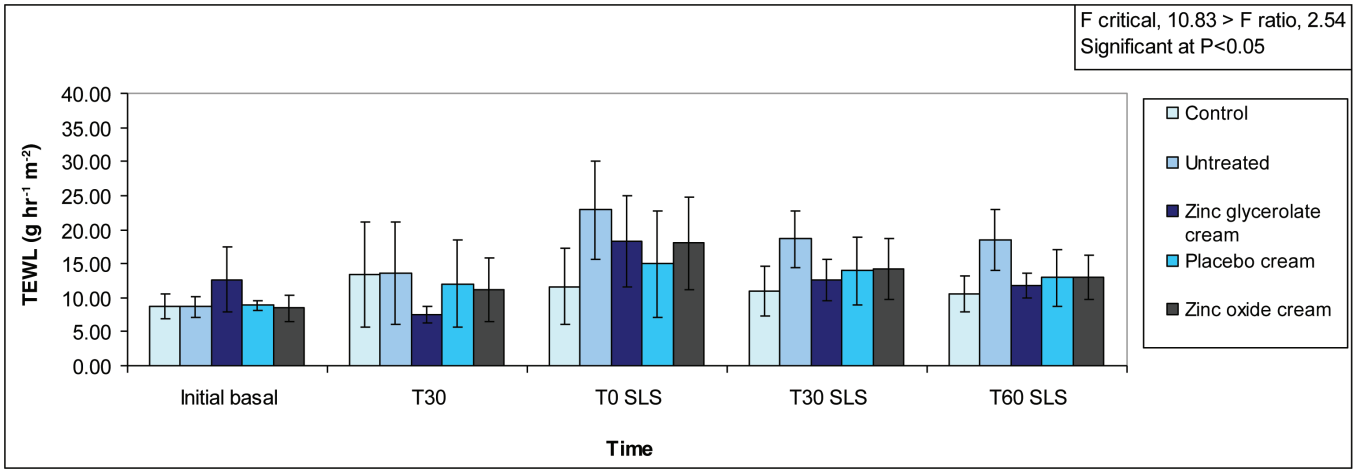

Figure 3. Average skin TEWL results (g hr^{-1} m^{-2}) for diaper cream containing zinc glycerolate, commercial diaper cream, placebo cream, untreated and control of barrier effect study before and after treatment with SLS discs. Significant at p=0.05 using ANOVA.

TABLE 2. COMPARISON AMONG SKIN BARRIER SAMPLES AT 60 min PRIOR TO SLS TREATMENT

Dependent Variable: Transepidermal water loss (TEWL)						
Sample (I)	**Sample (J)**	**Mean difference (I-J)**	**Std. error**	**Sig.**	**95% Confidence interval**	
					Lower bound	**Upper bound**
Untreated	Zinc glycerolate cream	3.8792*	0.887	0.000	1.4429	6.3155
	Commercial	3.5083*	0.887	0.001	1.0720	5.9446
	Placebo	3.8800*	0.887	0.000	1.4437	6.3163
	Control	5.4000*	0.887	0.000	2.9637	7.8363

Note: * Significant at p=0.05 using Tukey test.

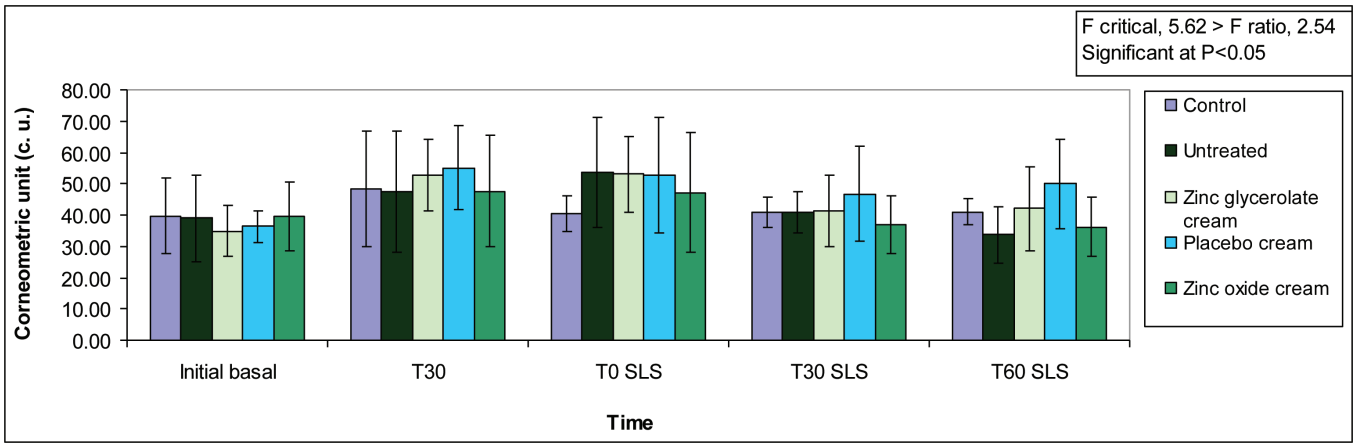

Figure 4. Average skin hydration results (corneometric unit, c.u) for diaper cream containing zinc glycerolate, commercial diaper cream, placebo cream, untreated and control of barrier effect study before and after treatment with SLS discs. The result is significant at p=0.05 using ANOVA.

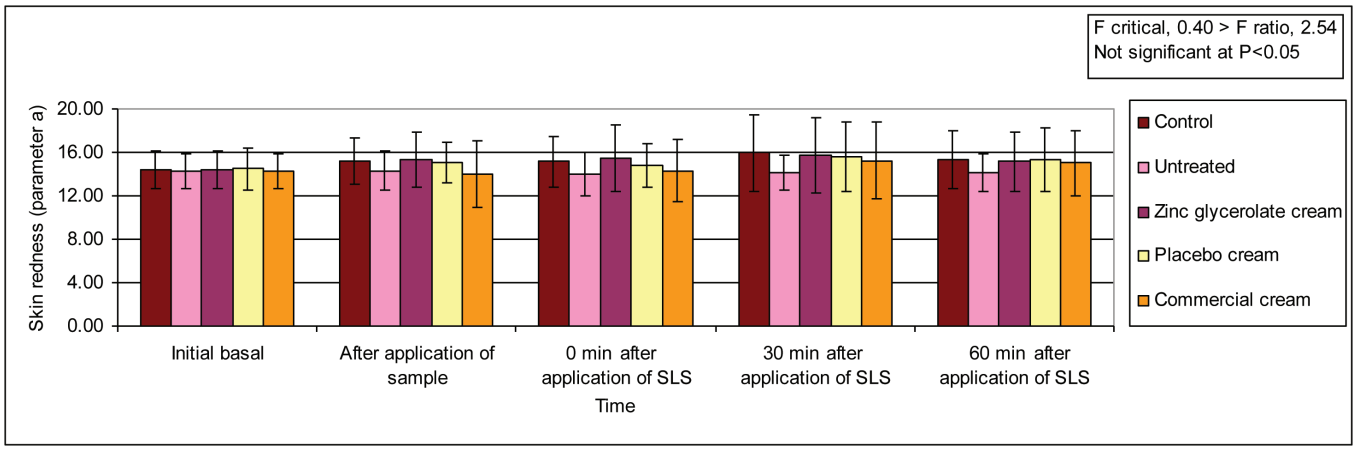

Figure 5. Average chromameter results (skin redness) for diaper cream containing zinc glycerolate, commercial diaper cream, placebo cream, untreated and control are as obtained from barrier effect study before and after treatment with SLS discs.

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